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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,508	07/13/2001	Charles Abbas	1533.0830003/MAC/RGM	3856

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,508	Applicant(s) ABBAS ET AL.	
	Examiner David A Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to an isolated polynucleotide sequence, an expression vector containing said sequence, cells containing said vector and methods for transforming the yeast, classified in class 435, subclass 320.1.
- II. Claim 22, drawn to mutant *Candida formata* strains, classified in class 435, subclass 254.22.
- III. Claim 23-28, drawn to a method of recovering riboflavin using yeast strains comprising multiple biosynthesis genes, classified in class 435, subclass 471.
- IV. Claims 29-31, drawn to a method of obtaining yeast with altered properties by treating them with compounds, classified in class 435, subclass 244.

Claim 22 is claimed in a Markush type format; however the members of the group do not possess unity of invention and instead are patentably distinct inventions recited in the alternative. The members of the group are different and patentably distinct from each other because each member comprises a different mutation, therefore there is no functional relationship between the members of the group (See MPEP 803.02). Upon election of Group II, Applicant is required to elect one member of the group set forth in the claim as follows: *rib2*, *rib1* (including VKMY-9L20105), *rib5*, *rib6*, mutant #105, *rib3* or *rib7* mutants. This is not an election of species.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims 2, 14 and 21 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, a single independent and distinct nucleotide sequence will be examined in a single application.

Claims 2, 14 and 21 specifically claim nucleotide sequences SEQ ID NOS 1-3. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence and therefore each has a distinct structure and function. Furthermore, a search of more than one (1) of the sequences claimed in claim 2, 14 and 21 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence when electing Group I as set forth above. This is not an election of species requirement.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Group I is directed to methods for transforming yeast with a polynucleotide

sequence represented by one of SEQ ID NOS: 1-3 and the resulting yeast strains. Group II is directed towards isolated yeast mutants that are not represented by yeast strains made in the methods of Group I, and the polynucleotides represented by SEQ ID NOS: 1-3 do not appear to confer the ability to make the mutants of Group II. There is no clear functional relationship between the two Groups, nor is there a disclosed method for using them together.

Inventions Group I and Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used for a materially different process, such as the production of any of the polypeptide sequences encoded by SEQ ID NOS: 1-3.

Inventions Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a materially different product, evidenced by the ability to obtain riboflavin from a number of genetically divergent yeast strains representing patentably distinct inventions, as listed in the Markush group of claim 22. Alternatively, the cells of Group II can be transformed with a vector comprising a heterologous gene for the purpose of purifying the encoded polypeptide.

Inventions Groups II and Group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product claimed could be made by a materially different process, such as the site-directed mutagenesis of a gene previously found to confer the desired biological properties.

Inventions Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not capable of use together. Group III is a method directed towards the recovery of riboflavin from yeast and the method of Group IV is a method of obtaining yeast with altered biological properties. There is no clear functional relationship between the two methods as each involves different method steps (such as the riboflavin isolation step in claim 23 versus the treatment of cells with mutagenic agents in claim 30) directed towards a different outcome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the non-patent literature searches required for each Group would not be co-extensive hence a simultaneous search of all the claims would be burdensome.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
December 10, 2002


PATENT EXAMINER